

## REMARKS

After entry of this Response, Claims 1-2, 4, 6, 8, 21-28, 31-35, and 38-39 are pending in the present application. By this Response, Claims 1, 4, 38 and 39 are amended, and Claims 3, 12, 29-30, 36 and 37 are canceled. The amendments to the claims are supported by the application as originally filed, and do not introduce new matter. It is respectfully submitted that the present application is in condition for allowance.

### REJECTION OF CLAIMS 1-4, 6, 8, 12, AND 21-39 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-4, 6, 8, 12, and 21-39 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants have amended the claims and respectfully submit that this rejection is moot. Applicants request that the Examiner withdraw this rejection.

### REJECTION OF CLAIMS 1-4, 6, 8, 12, AND 21-39 UNDER 35 U.S.C. § 112, 2ND PARAGRAPH

Claims 1-4, 6, 8, 12, and 21-39 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that the claims were “incomplete for omitting essential elements”, and that the omitted element is “the reactant produces oxygen... because the oxygen cannot be produced by catalyst without oxygen source”. Applicants have amended the claims and respectfully request the Examiner to withdraw the rejection.

### REJECTION OF CLAIMS 1-4, 6, 8, 12, AND 21-39 UNDER 35 U.S.C. § 103(a)

Claims 1-4, 6, 8, 12, and 21-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2002/0042587 (herein

“US ‘587”) and U.S. Patent No. 5,792,090 (herein “US ‘090”). Applicants respectfully traverse this rejection in view of the present amendments.

The Examiner stated that "it would be obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam that can be produced chemically as disclosed by US ‘587, and produce foam by oxygen gas delivered by the reaction of hydrogen peroxide and catalyst and replace the polymer by polyacrylamide as disclosed by US ‘090.....” (See Office Action, page 6). The Examiner’s stated that the “ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. §103 (a).” (See Office Action, page 10)

Three criteria must be met if a *prima facie* case of obviousness is to be established. There must be some motivation or suggestion to modify the reference; there must be a reasonable expectation of success; and the references must teach or suggest all the claim limitations. Applicants respectfully submit that the currently amended claims are not obvious, and not *prima facie* obvious, in view of the combination of the teachings of the cited references.

The obviousness rejection relies on US ‘090 solely for the “teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide” and “the cross-linked polymer matrix is taught by Murdock, but Murdock does not specifically teach polyacrylamide.” .... “[T]his would have motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by Murdock (US ‘587) with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as disclosed by US’090.” (Office Action, page 9)

If the proposed modification of the reference would render the prior art invention being modified unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. (*In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). Applicants respectfully submit that the polymer of US ‘587 cannot be replaced with polyacrylamide without altering the entire teaching of US ‘587, and rendering the US ‘587 matrix material unsatisfactory for its intended purpose. US ‘587 requires that

the polymeric material be foamed and then cross-linked, but a liquid solution of polyacrylamide cannot be foamed by oxygen, provided in any fashion or by the reaction of catalyst and hydrogen peroxide, and then cross-linked to form a matrix material. Polyacrylamide does not polymerize sufficiently in the presence of oxygen. The resulting material would not function as the drug delivery matrix taught in US '587.

There is no reasonable expectation of success in the modification of US '587 by the substitution of a polyacrylamide polymer matrix and production of oxygen by a catalyst and hydrogen peroxide. The Examiner states that "US '587 does not teach the chemical reaction that would produce the gas in the foam as claimed in claim 1". (see Office Action, page 5) US '587 teaches creating a foam by "foaming a therapeutic agent-containing polymeric matrix and cross-linking the foamed matrix." (See US '587, ¶ 34) Foaming the polymer matrix "may be accomplished by any chemical or physical method known in the art", but there is no teaching provided of chemical methods. Regardless of the method of foaming, the foaming step must precede the cross-linking step, (See US '587, teaching throughout, and Claim 1, wherein step b) is foaming to produce a polymeric foam matrix; followed by step c) cross-linking the polymeric foam matrix). The polymeric material taught by US '587 must be capable of being foamed first and then cross-linked. This requirement defines the teaching of US '587 of which polymeric materials can be used in the foam production- only those that can be foamed first, and then cross-linked.

The Examiner's rejection would use the teaching of US '090 of polyacrylamide in wound dressings for obvious replacement in the polymer matrix of US '587. Applicants respectfully submit that the only teaching of polyacrylamide as relied on for the rejection is a teaching in US '090 of an occlusive covering that provides a layer for moisture provision and may or may not form an integral part of the dressing taught in US '090. (See US '090, Col. 4, lines 28-43) The occlusive covering is not capable of delivery of oxygen, and does not provide a teaching or suggestion of oxygen delivery.

The requirement of US '587 that the polymeric solution be first foamed and then cross-linked cannot be met by a substitution of polyacrylamide when the gas of foaming

is oxygen because polyacrylamide does not polymerize in the presence of oxygen. The required second step of US '587, cross-linking of the foamed material, cannot be performed using polyacrylamide. Thus, it is not an obvious modification to "replace the polymer matrix disclosed by Murdock [US '587] with polyacrylamide matrix" when the gas for foaming is oxygen. No matrix will be formed. A matrix made using this modification would not function for the purpose intended by US '587.

The '090 patent teaches a reservoir that, among other alternatives, "may be a sponge-like or open-celled foam of natural, synthetic or mixed natural/synthetic origin". There is no teaching or suggestion in the '090 patent of closed cells, or the entrapment of oxygen within closed cells. A catalyst is present in the reservoir and will produce oxygen in a "renewable and non-sustaining" manner, when contacted by a supplied liquid. (see '090, Col. 5, lines 59-60. 65-Col. 6, line 3). There is no teaching of polyacrylamide specifically for this reservoir, nor is there a teaching of closed cells containing oxygen at any site in the reference. There is a teaching of production of oxygen by the contacting of a catalyst with hydrogen peroxide. The combination of a reservoir containing, in some fashion, a sponge and a catalyst does not provide a teaching of a polymer matrix comprising closed cells containing a gas produced by the reaction of a catalyst with a reactant solution. US '090 does not provide a teaching for the modification of US '587 that has a reasonable expectation of success in resulting in a polymeric matrix that functions in its intended manner.

Applicants are not arguing that the prior art devices are not physically combinable, instead, Applicants are pointing out that one of skill in the art would not have been motivated to make the modifications of US '587, by the teachings of US '090 of polyacrylamide and oxygen production from a catalyst plus hydrogen peroxide. The combined teaching, which results in a polyacrylamide matrix that cannot be polymerized, renders US '587 inoperable for its intended purpose.

There is no teaching or suggestion in the cited references of all of the claim limitations of the currently amended claims. Neither of the references, singly or in combination, teach an oxygen-containing polymeric matrix wherein the oxygen is found

in closed cells that are formed in a cross-linked matrix. Thus, a rejection of the currently amended claims as being *prima facie* obvious is not supported. The modification of US '587 by polyacrylamide and oxygen production as suggested by US '090 would not be made by one skilled in the art because the modifications render the modified matrix incapable of being polymerized, and it cannot fulfill its intended purpose, and the combination of references does not teach every claim limitation as currently pending.

Applicants have previously submitted a Declaration showing that the invention of the pending claims possesses improved properties not expected by the prior art. The Declaration showed that the polymeric matrix dressing of the presently pending claims had superior oxygen provision (5.6 and 13 times the US '587 device), showed oxygen delivery kinetics that were unlike the prior art device, (increasing oxygen release compared to static release by the US '587 device); contains more oxygen and released more oxygen than the US '587 device. After 24 hours in water, the US '587 device had changes in structural characteristics, such as loss of structural integrity, whereas the current invention had no loss of structural integrity. The Declaration is directed to the presently pending claims and provided objective evidence of the nonobviousness of the currently pending invention.

For at least these reasons, Applicants respectfully submit that the currently pending claims are not obvious in view of US '587 and the modifications of US '090. Applicants request that the Examiner withdraw the rejection.


## CONCLUSION

The foregoing is a complete response to the Office Action mailed June 6, 2007. Applicants believe that the Office Action has been fully responded to, and that each of the claims is in condition for immediate allowance. Applicants respectfully request reconsideration and allowance of all pending claims.

Applicants are including a Petition for a one month extension of time and the appropriate fee, in addition to the Request for Continued Examination and the appropriate fee. Applicants do not find that any other fees are currently due, but the Commissioner is hereby authorized to charge any other fees that may be required, or to credit any overpayment, to Deposit Account No. 20-1507.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 885-3652 is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mary A. Merchant', with a stylized flourish at the end.

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